DEC - 1 2011

K112296

510(k) Summary of Safety & Effectiveness

Pursuant to CFR 807.92, the following 510(k) Summary is provided:

1. (a)	**Submitter Address:**	George J. Hattub MedicSense, USA 291 Hillside Avenue Somerset, MA 02726 www.medicsense.com
1.	***Manufacturer Address:***	T.A.G. Medical Products Corporation, Ltd. D. N. Ashrat Kibbutz Gaaton 25130, Israel
	Mfg. Phone:	Tel.: +972-4-985-8400
	Contact Person:	Erez Adiv
	Date:	November 30, 2011
2.	***Regulation Description Device & Classification***	Regulation number 21 CFR 888.3040 Smooth or threaded metallic bone fixation fastener Device class: 2 Product code MBI
	Name:	Lateral Button™
3.	***Predicate Devices:***	K970423 - Innovasive Devices, Inc.
4.	***Description:***	The Lateral Button™ consists of an implanted Button preloaded on a disposable inserter necessary for its insertion into the bone tunnel, the inserter is removed upon completion of the procedure. The implant is made of implantable grade PEEK (polyether - etherketone). The inserter is made of Polycarbonate. The Lateral Button and its inserter will be supplied sterile for single use. The implant has an O.D. of 3.1 mm, overall length of 10 mm and an I.D. of 1.8 mm. In use, the suture is threaded through the implant, which helps to distribute the pressure created by the suture and assists in the prevention of suture migration and damage to suture and/or bone. The implant will be supplied either as a stand alone device or as part of a kit i.e. with other devices already cleared for transosseous fixation procedures.
5.	***Intended Use:***	The Lateral Button™ is intended to protect the suture / bone during transosseous fixation procedures
6.	***Comparison of Technological Characteristics:***	With respect to its indication for use, the Lateral Button is substantially equivalent to its predicate devices in that is intended for the same clinical purpose. * With respect to technology, the performance is the same as verified by design verification. This consisted of static and dynamic testing in which the results demonstrated substantial equivalence to the predicate device. The material used PEEK (polyether - etherketone) is a standard material used in surgical implant applications. Based upon this, T.A.G. Medical Products Corporation, Ltd. believes that its device is safe and effective because it performs and functions in the same manner.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

T.A.G. Medical Products Corporation, Ltd.
% MedicSense, USA
Mr. George Hattub
291 Hillside Avenue
Somerset, Massachusetts 02726

DEC - 1 2011

Re: K112296
Trade/Device Name: Lateral Button™
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: MBI
Dated: November 14, 2011
Received: November 18, 2011

Dear Mr. Hattub:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K112296

Indications for Use

510(k) Number (if known):

Device Name: Lateral Button™

Indications For Use: The Lateral Button™ is intended to protect the suture/bone during transosseous fixation procedures.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K112296